



Complete Summary

GUIDELINE TITLE

Pain.

BIBLIOGRAPHIC SOURCE(S)

Work Loss Data Institute. Pain. Corpus Christi (TX): Work Loss Data Institute; 2006. 196 p. [228 references]

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- On April 7, 2005, U.S. Food and Drug Administration (FDA) asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the [FDA Web site](#) for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the [FDA Web site](#) for more information.

- On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta (duloxetine hydrochloride), indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with any hepatic insufficiency. See the [FDA Web site](#) for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

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SCOPE

DISEASE/CONDITION(S)

Work-related pain (acute and chronic)

GUIDELINE CATEGORY

Diagnosis

Evaluation

Management

Treatment

CLINICAL SPECIALTY

Family Practice

Internal Medicine

Neurological Surgery

Neurology

Physical Medicine and Rehabilitation

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Health Plans
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To offer evidence-based step-by-step decision protocols for the assessment and treatment of workers' compensation conditions

TARGET POPULATION

Workers with work-related pain

INTERVENTIONS AND PRACTICES CONSIDERED

The following interventions/procedures were considered and recommended as indicated in the original guideline document:

1. Acupuncture
2. Antidepressants (Note: Use of selective serotonin reuptake inhibitors [SSRIs] versus tricyclic antidepressants as first-line therapy is under study and is not specifically recommended)
3. Anti-inflammatory medications (e.g., ibuprofen, nonsteroidal anti-inflammatory drugs [NSAIDs], Celebrex)
4. Behavioral interventions
5. Botulinum toxin (Botox)
6. Capsaicin
7. Cod liver oil
8. Cyclobenzaprine (Flexeril®)
9. Duloxetine (Cymbalta)
10. Education
11. Electrodiagnostic testing (electromyography [EMG] and nerve conduction studies [NCS])
12. Epidural steroid injections (ESIs)
13. Exercise
14. Gabapentin (Note: Not a U.S. Food and Drug Administration (FDA) approved indication)
15. Glucosamine (and chondroitin sulfate)
16. Implantable drug-delivery systems (IDDSs)
17. Interdisciplinary rehabilitation programs
18. Lumbar sympathetic block
19. Medications
20. Multi-disciplinary pain programs
21. Muscle relaxants for acute back pain (Not recommended for chronic pain)
22. Nonprescription medications (acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs])
23. Phentolamine infusion test
24. Physical therapy/occupational therapy
25. Psychological evaluations

26. Return-to-work
27. Salicylate topicals
28. Stellate ganglion block
29. Trigger point injections for myofascial pain syndrome only
30. Yoga

The following interventions/procedures are under study and are not specifically recommended:

1. Autonomic test battery
2. H-wave stimulation (devices)
3. Injection with anesthetics and/or steroids
4. Intravenous regional sympathetic blocks (for reflex sympathetic dystrophy [RSD], nerve blocks)
5. Ketamine
6. Massage therapy
7. Neuromuscular electrical stimulation (NMES devices)
8. Neuroreflexotherapy
9. Percutaneous electrical nerve stimulation (PENS)
10. Sympathetic therapy
11. Transcutaneous electrical nerve stimulation (TENS)
12. Treatment for complex regional pain syndrome (CRPS)

The following interventions were considered, but are not recommended:

1. Barbiturate-containing analgesic agents
2. Biofeedback
3. Electroceutical therapy (bioelectric nerve block)
4. Facet blocks
5. Galvanic stimulation
6. Interferential current stimulation (ICS)
7. Low level laser therapy (LLLT)
8. Magnet therapy
9. Manual therapy and manipulation
10. Microcurrent electrical stimulation (MENS devices)
11. Nucleoplasty
12. Opioids as primary treatment
13. Percutaneous neuromodulation therapy (PNT)
14. Prolotherapy/sclerotherapy
15. Pulsed radiofrequency treatment (PRF)
16. Spinal cord electrical stimulators
17. Sympathectomy
18. Therapeutic ultrasound
19. Thermography (Not recommended except possibly for CRPS)
20. Vioxx (withdrawn from the U.S. and worldwide market)

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Ranking by quality within type of evidence:

- a. High Quality
- b. Medium Quality
- c. Low Quality

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Note from the National Guideline Clearinghouse (NGC): For the Work Loss Data Institute's "Disclaimer: limitations of scope" statement, refer to the "Qualifying Statements" field in this summary or see the original guideline document.

Initial Diagnosis

The International Association for the Study of Pain (IASP) has described pain as an experience rather than a sensation. As with any experience, the feeling of pain will be different in every patient based on personal and cultural factors, both mental and physical. Physician-patient communication enables the physician to understand the origin and the reason for the pain. Pain without evidence of tissue damage or pain that is felt after an injury has healed is no less "real" to the patient than pain in its acute stage. The key to managing pain is to focus on restoring function, rather than eliminating pain.

Initial Evaluation

- Determine if there was a specific incident that caused or triggered the onset of pain.
- Determine whether the problem is acute, subacute, chronic, or of insidious onset.
- Determine the severity and specific anatomic location of the pain.
- Assess the ability of the patient to perform normal functions such as walking, lifting, sitting, and standing, especially as related to the patient's job.
- Determine any present medication.
- Determine any previous medical history, history of systemic disease, or history of previous pain or past injuries that could be causing or contributing to present pain.
- Even if there is no physical evidence to explain the pain, the physician should be careful not to trivialize the patient's experience of pain; trivializing the patient's complaints could only make the patient exaggerate the symptoms in order for the pain to seem more real to the physician.

Presumptive Diagnosis

- Acute pain is a sign of real or impending tissue damage and usually disappears with healing, although the experience may still be different based on personal factors.
- Chronic pain exists when the patient continues to experience pain even after the injury has healed. Early detection of potential chronic pain patients could help in determining treatment approach. Pain is not remembered, but the fear of pain is.
- Note: In workers' compensation cases, providers may need to shift focus from a "cure and relieve" to a "functional restoration" paradigm. Too much effort may be going into responding to complaints of pain rather than encouraging "coping" strategies and the desirable outcome of "working" with pain. There is a possibility of a "Wounded Worker Syndrome," which is a chronic pain condition characterized by failure of an injured worker to respond to conventional healthcare measures, and prolonged disability with continued absence from the workplace. This "Wounded Worker" chronic pain syndrome is facilitated by a healthcare system that encourages and supports the injured worker in his "sickness" role.

Official Disability Guidelines (ODG) Return-To-Work Pathways

Myalgia and Myositis, Unspecified (Muscle Pain or Inflammation) (see original guideline document for ICD-9 codes for this and other diagnoses)

Moderate pain: 0 days

Debilitating pain, with hospitalization, modified work: 14 days

Debilitating pain, with hospitalization, regular work: 42 days

Myofascial pain syndrome, trigger point injection: 1-7 days

Myofascial pain syndrome, acupuncture: 7-21 days

Myofascial pain syndrome, physical therapy: 14-21 days

Fibromyalgia: Controversial and self-perpetuating diagnosis - see related conditions and return to regular activities as soon as possible

Reflex Sympathetic Dystrophy (including CRPS-I)

Note: this is a controversial diagnosis

Sympathetic nerve block: 3-7 days)

Complex regional pain syndrome (CRPS-I), early stage: 28-84 days

Complex regional pain syndrome (CRPS-I), late stage: 210 days to indefinite

Late stage reflex sympathetic dystrophy (RSD) (CRPS-I): 365 days to indefinite

Causalgia of Upper Limb (including CRPS-II)

Note: this is a controversial diagnosis

Medical treatment: 0 days

Sympathetic nerve block: 2 days

Complex regional pain syndrome (CRPS-II): 28-84 days

Causalgia of Lower Limb (including CRPS-II)

Note: this is a controversial diagnosis

Medical treatment: 0 days

Sympathetic nerve block: 2 days

Complex regional pain syndrome (CRPS-II): 28-84 days

Mononeuritis of Unspecified Site (including CRPS-II)

Note: this is a controversial diagnosis

Sympathetic nerve block: 3-7 days

Complex regional pain syndrome (CRPS-II), early stage: 28-84 days

Complex regional pain syndrome (CRPS-II), late stage: 210 days to indefinite

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

During the comprehensive medical literature review, preference was given to high quality systematic reviews, meta-analyses, and clinical trials over the past ten years, plus existing nationally recognized treatment guidelines from the leading specialty societies.

The type of evidence associated with each recommended or considered intervention or procedure is ranked in the guideline's annotated reference summaries.

Ranking by Type of Evidence:

1. Systematic Review/Meta-Analysis
2. Controlled Trial-Randomized (RCT) or Controlled
3. Cohort Study-Prospective or Retrospective
4. Case Control Series
5. Unstructured Review
6. Nationally Recognized Treatment Guideline (from www.guideline.gov)
7. State Treatment Guideline
8. Foreign Treatment Guideline
9. Textbook
10. Conference Proceedings/Presentation Slides

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

These guidelines unite evidence-based protocols for medical treatment with normative expectations for disability duration. They also bridge the interests of the many professional groups involved in diagnosing and treating pain.

POTENTIAL HARMS

Adverse effects of medications

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Note from the Work Loss Data Institute: Disclaimer: limitations of scope. See body-part chapters for condition specific information, especially the Low Back Chapter. The Pain Chapter is focused on chronic pain, and also covers causalgia, complex regional pain syndrome (CRPS), myofascial pain, and generalized pain syndromes. Users not interested in those conditions, but on pain that is the result of conditions in specific body parts (e.g., low back, neck, or extremity pain), should also access those other chapters for management of pain of those body parts, although those chapters may refer to the Pain Chapter for certain generalized evidence summaries.
- The Treatment Protocol sections outline the most common pathways to recovery, but there is no single approach that is right for every patient and these protocols do not mention every treatment that may be recommended. See the Procedure Summaries (in the original guideline document) for complete lists of the various options that may be available, along with links to the medical evidence.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 (revised 2006)

GUIDELINE DEVELOPER(S)

Work Loss Data Institute - Public For Profit Organization

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available to subscribers from the [Work Loss Data Institute Web site](#).

Print copies: Available from the Work Loss Data Institute, 169 Saxony Road, Suite 210, Encinitas, CA 92024; Phone: 800-488-5548, 760-753-9992, Fax: 760-753-9995; www.worklossdata.com.

AVAILABILITY OF COMPANION DOCUMENTS

Background information on the development of the Official Disability Guidelines of the Work Loss Data Institute is available from the [Work Loss Data Institute Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 2, 2004. The information was verified by the guideline developer on February 13, 2004. This NGC summary was updated by ECRI on March 28, 2005. This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This NGC summary was updated by ECRI on January 13, 2006, and on April 11, 2006.

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